



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Market Review (Part 1) The European Generic Medicines Markets

Price and Reimbursement Systems

2011





2011 Market Review (Part 1) The European Generic Medicines Markets

Price and Reimbursement Systems

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The EGA's Health Economics Committee is pleased to present the EGA 2011 Market Review (Part one of three): Price and Reimbursement Systems.

This year, the European countries covered in this chapter are: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, The Netherlands, Norway, Poland, Portugal, Spain, Sweden, Turkey and the United Kingdom.

This first part of the 2011 Market Review addresses 10 major topics, namely: Generic Medicines Pricing Systems, Tendering Systems, Reimbursement Systems, Patient Co-payments, Patient Use of Generic Medicines, Generic Medicines Prescribing, Generic Medicines Substitution, Generic Medicines Distribution,

Marketing Authorisation and General Information about Generic Medicines of which the three underlined ones are new for this edition.

Throughout these different subsections, the user will have a clear view of how price and reimbursement systems are set in the reviewed countries. The user will also have a better understanding of the interactions at different levels of stakeholders in the European Generic Medicines Markets.

This document will be distributed to EGA Members as well as to those who have contributed to this project. The information gathered in this document has been sourced from the European Generic medicines Associations and EGA Company Members.

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EGA Director General



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Chair of the EGA Health Economics Committee



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| SECTION A/ B |

Generic Medicines Pricing System

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
A free pricing system?	No	No	No	No	No	Yes ¹	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	Yes	4	16	0	20
A price regulated system?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes ²	Yes	No	16	4	0	20
If you have a price regulated system, are prices set based on:																								
The average of selected EU countries	No	No	Yes	Yes	Yes	-	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	-	5	13	2	20
% below the originator	48%	30%	80%	30%	25%	-	40%	55%	No	30%	20% ³	30%	No	No	No	35 or 20%	40%	No	No	-	12	6	2	20
Maximum price	Yes	No	Yes	Yes	Yes	-	No	No	No	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	-	10	8	2	20
Negotiable	No	No	No	No	No	-	No	No	No	No	No	No	No	No	No	No	No	No	No	-	0	18	2	20
Other	No	No	No	No	No	-	Yes	Yes ⁴	Yes ⁵	No	Yes ⁶	No	No	No	Yes ⁷	No	No	No	Yes ⁸	-	6	12	2	20

¹ Although it is a free pricing system, tendering like system is in place

² If the reference product is not reimbursed, then the generic medicine version can be priced at any level

³ 20% below the originator price is the legal requirement but since the price is negotiated with the Medicine Agency this % ends up at -60% on average

⁴ If you are the first generic medicine, negotiation is possible

⁵ Maximum reference prices and tender business

⁶ Negotiable mechanisms are in place for specific biosimilar products and "under construction" for generic medicines

⁷ New proposal of health minister to introduce price/volume agreement

⁸ Negotiation mechanisms are in place to adjust prices upwards for low-price products

| SECTION C | Tendering System (1/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Has any kind of Tendering System been discussed in your country?	Yes	Yes	Yes ¹	No	Yes	Yes	Yes	Yes	Yes	Yes ²	Yes	No	Yes	No	No	Yes	No	Yes	No	Yes	14	6	0	20
If yes, who are the driving forces?																								
Government	No	Yes	Yes	-	Yes	No	No	No	Yes	No	Yes	-	No	-	-	Yes	-	No	-	Yes	7	7	6	20
Healthcare insurance funds	Yes	Yes	No	-	Yes	No	Yes	Yes	Yes	Yes	No	-	Yes	-	-	No	-	No	-	No	8	6	6	20
Other	No	No	No	-	No	Yes	No	Yes ³	No	No	Yes ⁴	-	No	-	-	No	-	Yes	-	No	4	10	6	20
Is it currently implemented?	No	No	Yes	-	No	No	No	No	Yes ⁵	Yes	No	-	Yes	-	-	No	No	No	-	No	4	11	5	20
Apart from tendering, is there another way generic medicines companies can access the market	-	-	No	-	-	-	-	-	-	No	-	-	Yes	-	-	-	-	-	-	-	1	2	17	20

¹ Tendering in the retail market exists for a small number of molecules only

² Not for generic medicines

³ MP members of Parliament

⁴ Local authorities (21 regions)

⁵ Classic distribution (wholesaler, pharmacy)



Tendering System (2/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
Could you please indicate which bodies are involved in the tendering system?																									
Government	-	-	No	-	-	-	-	-	No	No	-	-	No	-	-	-	-	-	-	-	-	0	4	16	20
Healthcare authorities	-	-	Yes	-	-	-	-	-	No	Yes	-	-	No	-	-	-	-	-	-	-	-	2	2	16	20
Healthcare insurance funds	-	-	No	-	-	-	-	-	Yes	Yes	-	-	No	-	-	-	-	-	-	-	-	2	2	16	20
Manufacturers	-	-	Yes	-	-	-	-	-	Yes	Yes	-	-	Yes	-	-	-	-	-	-	-	-	4	0	16	20
Others	-	-	No	-	-	-	-	-	No	-No	-	-	Yes	-	-	-	-	-	-	-	-	1	3	16	20
If you have a Tendering system, are prices negotiated for:																									
Whole Pharmaceutical Market	-	-	Yes	-	-	Yes	-	-	No	Yes	-	-	No	-	-	-	-	-	-	-	-	3	2	15	20
Off Patent Market	-	-	No	-	-	No	-	-	No	No	-	-	No	-	-	-	-	-	-	-	-	0	5	15	20
Other	-	-	No	-	-	No	-	-	Yes ¹	No	-	-	No	-	-	-	-	-	-	-	-	1	4	15	20

¹ Negotiations on discounts on new patented drugs

Tendering System (3/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
How are prices negotiated?																									
By active substance	-	-	Yes	-	-	-	-	-	Yes	No	-	-	Yes	-	-	-	-	-	-	-	-	3	1	16	20
By product	-	-	Yes	-	-	-	-	-	Yes	Yes	-	-	Yes	-	-	-	-	-	-	-	-	4	0	16	20
By group of product	-	-	No	-	-	-	-	-	No	No	-	-	No	-	-	-	-	-	-	-	-	0	4	16	20
By therapeutic indication	-	-	No	-	-	-	-	-	Yes	No	-	-	No	-	-	-	-	-	-	-	-	1	3	16	20
Other	-	-	No	-	-	-	-	-	No	No	-	-	No	-	-	-	-	-	-	-	-	0	4	16	20
Is the tender awarded for:																									
The whole country	-	-	Yes	-	-	-	-	-	No	Yes	-	-	Yes	-	-	-	-	-	-	-	-	3	1	16	20
Per region	-	-	No	-	-	-	-	-	Yes	No	-	-	No	-	-	-	-	-	-	-	-	1	3	16	20



Tendering System (4/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
What is the contract duration of the tender?																									
Less than 1 year	-	-	Yes	-	-	Yes	-	-	No	No	-	-	-	-	-	-	-	-	-	-	-	2	2	16	20
1 to 6 months	-	-	No	-	-	No	-	-	No	No	-	-	-	-	-	-	-	-	-	-	-	0	4	16	20
More than 12 months	-	-	No	-	-	No	-	-	Yes	Yes	-	-	-	-	-	-	-	-	-	-	-	2	2	16	20
More than 24 months	-	-	No	-	-	No	-	-	No	No	-	-	-	-	-	-	-	-	-	-	-	0	4	16	20
Does the system allow more than one winner?	-	-	No	-	-	Yes	-	-	Yes ¹	Yes	-	-	No	-	-	-	-	-	-	-	-	3	2	15	20
After granting the tender, do price changes take place?	-	-	No	-	-	Yes	-	-	No	-	-	-	Yes	-	-	-	-	-	-	-	-	2	2	16	20
Is there a guaranteed volume as a result of winning the tender?	-	-	No	-	-	No	-	-	No	-	-	-	No	-	-	-	-	-	-	-	-	0	4	16	20

¹ Depends on the statutory Insurance fund (e.g. AOK= 1 winner; others up to 5 winners)

Tendering System (5/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Are factors other than the lowest price taken into account when determining the winner of the tender?	-	-	No	-	-	No	-	-	No	-	-	-	Yes	-	-	-	-	-	-	-	1	3	16	20
If yes, do those factors include:																								
Customer service	-	-	-	-	-	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	0	1	19	20
Ongoing patient support	-	-	-	-	-	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	0	1	19	20
Value-added presentation	-	-	-	-	-	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	0	1	19	20
Local manufacture	-	-	-	-	-	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	0	1	19	20
Most complete range of indication	-	-	-	-	-	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	0	1	19	20
Other	-	-	-	-	-	-	-	-	-	-	-	-	Yes	-	-	-	-	-	-	-	1	0	19	20
Is the "winning" price from the tender known to competitors?	-	-	Yes	-	-	Yes	-	-	No	-	-	-	Yes	-	-	-	-	-	-	-	3	1	16	20
Are you aware of shortage problems due to tendering?	-	-	No	-	-	No	-	-	Yes	-	-	-	Yes	-	-	-	-	-	-	-	2	2	16	20



Tendering System (6/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Can a company that did not win the tender access the market at any time during the tender?	-	-	No	-	-	No	-	-	Yes	-	-	-	Yes	-	-	-	-	-	-	-	2	2	16	20
Are you aware of any patient compliance problems?	-	-	No	-	-	No	-	-	Yes	No	-	-	No	-	-	-	-	-	-	-	1	4	15	20

| SECTION D | Reimbursement System (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Do you have a Reference Reimbursement System?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	16	4	0	20
If you have a Reference Pricing System, how is the Reference Price established?																								
• By active substance	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	No	-	Yes	No	Yes	-	Yes	-	14	2	4	20
• By pharmacological class	No	No	Yes	Yes	Yes	-	No	No	Yes	Yes	No	No	Yes	-	No	No	No	-	No	-	6	10	4	20
• By therapeutic class	No	No	No	Yes	Yes	-	No	No	Yes	Yes	No	Yes	No	-	Yes	No	No	-	No	-	6	10	4	20
• Other	No	No	No	No	No	-	No	No	No	No	Yes ¹	No	No	Yes ²	No	Yes ³	No	-	No	-	3	14	3	20

¹ By therapeutic class in some regions (statins and ppi)

² For originators, the full price is reimbursed until generic medicines competition. However, the originators full price is low compared to other European countries. Out of 9 other countries, the full price is the average of the 3 lowest prices

³ By active substance+ dosage+ pharmaceutical form+ pack size



Reimbursement System (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
If you have a Reference Pricing System, how is the Reference Price set?																								
• Based on the average price of medicines	No	No	No	Yes	No	-	No	No	-	Yes	No	No	No	-	No	No	No	-	No	-	2	13	5	20
• Based on the average price of generic medicines	No	No	No	No	No	-	No	Yes ¹	-	No	No	No	No	-	No	No	No	-	No	-	1	14	5	20
• Based on the lowest priced medicine	No	No	Yes	No	Yes	-	Yes	No	-	Yes	Yes	Yes	No	-	Yes	No	Yes	-	Yes	-	9	6	5	20
• Based on the lowest priced generic medicine	Yes	No	Yes	No	No	-	No	Yes	-	No	No	Yes	No	-	No	No	No	-	No	-	4	11	5	20
• Other	No	Yes ²	No	No	No	-	Yes	No	-	No	No	No	No	-	No	Yes ³	No	-	No	-	3	12	5	20

¹Based on the lowest price of the generic medicine (= average price as there is just one common price for generic medicines)

²When the generic medicine enters the market, the original molecule enters into the reference reimbursement system; i.e.: the reimbursement for the original decreases with 30, which is the maximum public price for the generic medicine

³Based on the average of 5 lowest priced generic medicines in an Homogeneous Group

Reimbursement System (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Are there different reimbursement categories for medicines?	Yes	Yes	Yes	Yes	Yes	-	Yes ¹	Yes ²	Yes	Yes	Yes ³	-	No	-	Yes	Yes	Yes	-	No	Yes ⁴	14	2	4	20
Are there positive and/or negative lists in your country?																								
Positive List	Yes	Yes	Yes	Yes	No	-	No	Yes	No	No	Yes	Yes	No	-	Yes	Yes	No	-	Yes	No	10	7	3	20
Negative List	Yes	No	No	No	No	-	No	No	Yes	No	No	No	No	-	No	No	No	-	No	Yes	3	14	3	20

¹ Basic reimbursement (42%), special reimbursement (lower special reimbursement 72 % and higher special reimbursement 100%)

² 100% (rare and exceptional drugs), 65% (this is the rule), 30% (efficiency of the medicine is not very high), 15% (medicine with weak clinical activity proofs)

³ CLASS A is the category of 100% reimbursed medicines (Rx bound) whether or not they are off patent. Those CLASS A medicines are sold mainly in the retail channel. Under CLASS A follows also medicines which are reimbursed only for specific diseases. In case the medicine is used for other diseases is not reimbursed. CLASS H, 100% reimbursed medicines sold in hospitals, CLASS C are not reimbursed

⁴ Different systems for brands (including branded generic medicines) and INN generic medicines



| SECTION E | Patient Co-Payment

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
Is there patient co-payment?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	18	1	1	20
If yes, which of the following is it based on:																									
Patient annual/ monthly consumption/ (DDD)	No	No	No	No	No	No	Yes	No	No	No	No	No	No	-	No	No	No	No	No	No	No	1	18	1	20
Fixed amount per prescription	No	No	No	Yes	Yes ¹	No	No	Yes	No	Yes	Yes	No	No	-	Yes	No	No	No	No	Yes	7	12	1	20	
% of cost of medicines (partially reimbursed)	No	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	-	Yes	Yes	Yes	Yes	Yes	No	12	7	1	20	
Difference above referenced price	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	-	Yes	Yes	No	No	Yes	No	13	6	1	20	
Other	Yes	No	No	Yes ²	No	Yes	No	No	No	No	Yes ³	No	Yes ⁴	-	No	No	No	No	No	No	5	14	1	20	
Does the patient co-payment differ for generic medicines?	No	No	-	No	Yes & No ⁵	No	No	No	Yes	No	-	No	No	-	No	No	No	-	No	-	2	12	6	20	

¹ Fixed amount per item on prescription

² Patient co-payment depends on the decision per product and per company when mutual agreement of accepting proposed reimbursed price is not met by MAH and healthcare fund

³ Regions are allowed to require the payment of a "ticket" on the medicinal prescription or pack

⁴ Difference above reimbursement price. For a product not being preferent in the preferent system (off-patent products): no reimbursement at all

⁵ It depends from drug to drug

| SECTION F |

Patient Use of Generic Medicines (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
What is the general public/ patient perception and attitude towards the use of generic medicines?																								
Positive	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No ¹	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	- ²	14	4	2	20
Negative	Yes	No	Yes	No	No	No	No	No	No	No	No ³	No	-	No	No	No	No	No	No	-	2	16	2	20
Has there been any study carried out on consumer attitudes towards use of generic medicines?	No	Yes ⁴	No	No	Yes ⁵	No	Yes ⁶	Yes ⁷	No	No	Yes ⁸	No	Yes	Yes ⁹	Yes	Yes ¹⁰	Yes ¹¹	Yes ¹²	Yes ¹³	No	12	8	0	20

¹ 50/50

² Neutral

³ 50/50

⁴ CRIOC study in relation to « cheap medicines »

⁵ In two recent studies conducted by STEM on behalf of CAFF

⁶ "Do people regard cheaper medicines effective? Population survey on public opinion of generic medicines substitution in Finland" - Pharmacoepidemiology and drug safety; 2011; 20:185-191

⁷ Sofres Institute

⁸ Assogenerici-Onda to be concluded in December 2009- "Generic medicines and women", Research International, April 2009

⁹ Study carried out in 2003, (2 years after generic medicines substitution was introduced)-no longer relevant for today's status

¹⁰ <http://www.insa.pt/sites/INSA/Portugues/Publicacoes/Outros/Paginas/ObservacapConsumoGenericos.aspx>

¹¹ 2006 AESEG Study

¹² Socialstyrelsen Government Body

¹³ IEIS conducted 2 public opinion surveys to analyse the perceptions of generic medicines in Turkey



Patient Use of Generic Medicines (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Have there been information campaigns targeting patients to inform them about generic medicines?	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes ¹	11	9	0	20
If yes, in which form?																								
TV campaign	No	-	-	Yes	Yes	-	No	No	No	-	Yes ²	No	-	-	-	Yes	Yes	-	-	No	5	6	9	20
Radio	No	-	-	Yes	Yes	-	No	No	No	-	No	Yes	-	-	-	Yes	Yes	-	-	No	5	6	9	20
Leaflets	Yes	-	-	Yes	No	-	No	Yes ³	Yes	-	No	No	-	-	-	No	Yes	-	-	No	5	5	10	20
Seminar & Conferences	No	-	-	Yes	No	-	No	No	No	-	No	Yes	-	-	-	No	No	-	-	No	2	7	9	20
Websites	No	-	-	Yes	Yes	-	Yes	Yes	Yes	-	Yes	No	-	-	-	Yes	Yes	-	-	No	8	3	9	20
Advertising	No	-	-	Yes	Yes	-	No	No	No	-	No	No	-	-	-	No	Yes	-	-	No	3	7	8	20
Other	No	-	-	No	No	-	No	Yes ⁴	No	-	No	-	-	-	-	No	No	-	-	Yes	2	8	10	20

¹ Organised by Government

² Research conducted for Assogenerici Communication Campaign 2011 was organised by Assogenerici and financed by member companies

³ AFSSAPS : les 7 règles d'or du médicament générique

⁴ Letter via Healthcare Insurance Funds

| SECTION G |

Generic Medicines Prescribing (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Are doctors encouraged to prescribe generic medicines?	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	No	Yes	13	7	0	20
• By budgetary restrictions	No	No	-	Yes	Yes	-	-	No ¹	Yes	No	Yes ²	-	No	-	-	No	No	No	-	Yes	5	8	7	20
• By budgetary incentives	No	No	-	No	No	-	-	Yes ³	Yes	No	No	-	No	-	-	No	Yes	No	-	Yes	4	9	7	20
• Other way	Yes ⁴	Yes ⁵	-	No	No	-	-	Yes ⁶	Yes ⁷	Yes ⁸	Yes ⁹	-	Yes	-	-	Yes ¹⁰	Yes ¹¹	Yes ¹²	-	Yes ¹³	11	2	7	20

¹ Only for medicines included in the "Répertoire des médicaments générique"

² Depending on the local authority. There are no national compulsory prescribing rules but regions are adopting local compulsory measures

³ 7€/patient/year with the CAPI (Contrat d'Amélioration des Pratiques Individuelles)

⁴ By health insurance fund visits

⁵ Doctors need to meet a "profile" (i.e. a percentage of their prescriptions, expressed in DDD) of cheap prescriptions

⁶ A specific sales force is paid by Social Security to visit doctors in order to explain their interest in prescribing generic medicines

⁷ Sometimes, doctors can have a kickback provision if they prescribe generic medicines that are part of the discount contract between health insurance funds and manufacturers

⁸ By punitive measures

⁹ Drugs consumption is monitored by regional health authorities that encourage doctors to prescribe generic medicines or cheapest products at the first level

There are not compulsory prescribing rules

¹⁰ Over last 2 years, by campaigns promoting generic medicines

¹¹ Extra budget for supply resources

¹² Prescribers are encouraged to prescribe generic medicines but the medicines will be substituted at the pharmacies anyway. So many of them don't see any point in looking at price if there is an unpatented substance

¹³ Students are trained to prescribe generic medicines



Generic Medicines Prescribing (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Are doctors legally required to prescribe by INN?	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No	No	Yes	4	16	0	20
Only for reimbursement products?	-	-	-	-	-	-	-	Yes ¹	-	-	-	-	No	-	-	Yes	-	-	-	-	2	1	17	20
For all products?	-	-	-	-	-	-	-	No	-	-	-	-	No	-	-	No	Yes	-	-	-	1	3	16	20
Are doctors encouraged to prescribe by INN?	-	Yes	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	Yes	Yes	No	No	Yes	6	13	1	20
Are doctors assisted in generic medicines prescribing?	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	-	Yes	Yes	Yes	No	Yes	13	6	1	20
If yes, by the dissemination of prescribing information	No	No	-	-	No	-	Yes	No	Yes	No	No	-	No	-	-	Yes	No	No	-	Yes	4	9	7	20
By computerised prescribing	Yes	Yes	-	-	Yes	-	No	Yes	Yes	Yes	No	-	Yes	-	-	Yes	Yes	Yes	-	Yes	11	2	7	20
By a medicine database	No	Yes	-	-	Yes	-	Yes	No	No	Yes	No	-	No	-	-	Yes	Yes	No	-	Yes	7	6	7	20
By prescribing guidelines from an independent body	No	Yes	-	-	No	-	Yes	No	Yes	Yes	Yes	-	No	-	-	No	No	Yes	-	Yes	7	6	7	20
By prescription audits	No	Yes	-	-	No	-	Yes	Yes	Yes	Yes	Yes	-	No	-	-	No	No	No	-	Yes	7	6	7	20
By health insurance funds visits	Yes	No	-	-	No	-	No	Yes	Yes	No	No	-	Yes	-	-	No	No	No	-	No	4	9	7	20
Other way	No	No	-	Yes ²	No	-	No	No	No	No	No	-	No	-	-	No	No	No	-	No	1	13	6	20

¹ Only medicines included in the "Répertoire des médicaments génériques"

² There is pressure on doctors from the Croatian Healthcare Fund to cut expenditure which could be understood as an assistance to prescribe generic medicines

| SECTION H |

Generic Medicines Substitution (1/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Is generic medicines substitution legally allowed?	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	15	5	0	20
Can doctors prevent generic medicines substitution?	-	-	-	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	-	14	1	5	20
If yes: by a ticking box	-	-	-	-	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	No	-	9	6	5	20
By writing	-	-	-	-	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	-	9	6	5	20
By stamping	-	-	-	-	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	-	2	13	5	20
Other way	-	-	-	-	No	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes ¹	No	-	2	13	5	20
Is it compulsory for a pharmacist to substitute?	-	-	-	-	No	No	Yes	Yes	Yes	No	No	No	No	Yes	No	No	Yes	Yes	No	-	6	9	5	20

¹ By signature if it is medically motivated



Generic Medicines Substitution (2/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
According to legislation, when a doctor prescribes a <u>branded original product</u> that is out of patent, the pharmacist will dispense:																								
Any generic medicine, <u>on advice from the doctor</u>	-	No	No	No	No	-	No	No	-	No	No	Yes	No	-	-	No	-	No	No	-	1	12	7	20
Any generic medicine, <u>without advice from the doctor</u>	-	No	No	No	Yes	-	Yes	Yes	-	Yes	No	Yes	Yes	-	-	No	-	No	No	-	6	7	7	20
A cheaper generic medicine available, <u>on advice from the doctor</u>	-	No	No	No	No	-	No	No	-	No	No	Yes	No	-	-	No	-	No	No	-	1	12	7	20
A cheaper generic medicine available, <u>without advice from the doctor</u>	-	No	No	No	No	-	-	No	-	Yes	No	Yes	No	-	-	No	-	No	No	-	2	10	8	20

Generic Medicines Substitution (3/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
According to legislation, when a doctor prescribes a <u>branded generic</u> medicine, the pharmacist will dispense:																								
Any generic medicine, <u>with</u> reference to the doctor	-	-	No	No	-	No	No	No	No	No	No	-	No	-	No	No	-	No	No	-	0	13	7	20
Any generic medicine, <u>without</u> reference to the doctor	-	-	No	No		No	Yes	Yes	No	Yes	No	-	Yes	-	Yes	No	-	No	No	-	5	8	7	20
The cheapest generic medicine available, <u>with</u> reference to the doctor	-	-	No	No	-	No	No	No	No	No	No	-	No	-	No	No	-	No	No	-	0	13	7	20
The cheapest generic medicine available, <u>without</u> reference to the doctor	-	-	No	No	-	Yes	No	No	Yes	No	Yes	-	No	-	No	No	-	No	No	-	3	10	7	20
A cheaper generic medicine available, <u>with</u> reference to the doctor	-	-	Yes	No	-	No	No	No	No	No	No	-	No	-	No	No	-	No	No	-	1	12	7	20
A cheaper generic medicine available, <u>without</u> reference to the doctor	-	-	No	Yes	-	No	Yes	No	No	Yes	No	-	No	-	No	No	-	No	No	-	3	10	7	20



Generic Medicines Substitution (4/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Other	-	-	No	-	Yes ¹	-	-	No	-	-	Yes ²	Yes ³	-	-	-	Yes	Yes ⁴	-	-	Yes ⁵	6	2	12	20
According to legislation, when a doctor prescribes a medicine using INN, the pharmacist will dispense:																								
The original medicine	-	No	-	No	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	Yes	3	15	2	20
Any generic medicine	-	Yes	-	No	No	No	No	Yes	No	Yes	No	Yes	Yes	No	No	No	No	No	No	Yes	6	12	2	20
The cheapest generic medicine available	-	Yes	-	No	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	Yes	Yes	No	No	6	12	2	20
A cheaper generic medicine available	-	No	-	No	No	No	Yes	No	Yes	Yes	No	Yes	No	No	No	No	No	No	No	No	4	14	2	20
Other	-	No	-	Yes	Yes ⁶	No	No	No	No	No	Yes ⁷	No	No	Yes ⁸	Yes ⁹	Yes ¹⁰	No	No	No	No	6	12	2	20

¹ It depends on the availability of the drug prescribed, patient request for lowest co-payment and reimbursement level

² The cheapest product available, as far as its public price is aligned with the reference price, without advice from the doctor. Usually, the reference price is a generic medicine but it can happen that a non generic medicine determines the reference price for the molecule. The rule is: pharmacists can substitute only if there is a difference in price between original prescribed product and any other equivalent product; If the price is the same the substitution is not allowed

³ Mainly dispense the branded generic medicine written on Rx, but can offer the cheaper generic medicine available

⁴ Branded generic medicines

⁵ Whichever brand which has been prescribed

⁶ Depends on availability of the drug prescribed, patient request for lowest co-payment and reimbursement level

⁷ The cheapest product available, as far as its public price is aligned with the reference price, without advice from the doctor. Usually, the reference price is a generic medicine but it can happen that a non generic medicine determines the reference price for the molecule. The rule is: pharmacists can substitute only if there is a difference in price between original prescribed product and any other equivalent product; If the price is the same the substitution is not allowed

⁸ Pharmacies dispense only according to a positive list

⁹ No regulation

¹⁰ If the doctor prescribes a branded original and he prevents generic medicines substitution by ticking a box, the pharmacist will dispense the original. Otherwise, he will dispense any generic medicines available without reference to the doctor, informing the patient about the cheapest generic medicine available

Generic Medicines Substitution (5/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
If substitution is permitted, are pharmacists obliged to inform patients of substitution	-	-	-	No	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	-	13	1	6	20
Can the patient refuse the substitution?	-	-	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	-	15	0	5	20



Generic Medicines Substitution (6/6)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
How are pharmacists remunerated?																									
Higher margin than originator product	-	-	No	No	-	No	-	No	-	-	-	No	-	-	-	No	-	No	No	Yes	1	8	11	20	
Lower margin than originator product	-	-	No	No	-	No	-	No	-	Yes	-	No	-	-	-	No	-	Yes	No	No	2	8	10	20	
Percentage (%) per prescription	-	-	No	No	Yes	No	-	No	-	-	-	No	-	-	-	No	-	-	No	No	1	8	11	20	
Guarantee of absolute margin as originator	-	-	No	No	-	No	-	Yes	-	-	-	No	-	-	Yes	Yes	-	No	No	No	3	7	10	20	
Generic medicines substitution rate	-	-	No	No	-	No	-	No	-	-	-	No	-	-	-	No	-	-	No	No	0	8	12	20	
Fixed amount per prescription	-	-	No	Yes	Yes	No	-	No	Yes	-	-	No	Yes	-	-	No	-	No	No	Yes	5	7	8	20	
Other	-	-	No	No	-	Yes ¹	-	Yes ²	-	-	Yes ³	-	-	Yes ⁴	-	-	-	-	-	-	4	2	14	20	
When a pharmacist substitutes with a generic medicine, is he rewarded?	No	No	No	No	No	No	No	Yes ⁵	No	No	Yes	No	No	No	No	No	No	No	No	-	2	17	1	20	
Is any form of therapeutic substitution allowed?	No	No	No	No	No	No	No	Yes ⁶	No	No	No	No	No	Yes	No	No	-	No	No	No	2	17	1	20	

¹ Like all medicines, it is a fixed percentage based on the sale price

² "Generic medicines" discount on invoice (17%)

³ Reimbursed medicines: fixed margin on public price for generic medicines: companies (58.65%), wholesalers (6.65%), pharmacists (26.7%). The remaining 8% is distributed, according to market forces, to the supply chain as an incentive to dispense generic medicines

⁴ Pharmacies are owned by wholesalers- the isolated pharmacy margin is decreased with lower generic medicines prices- however, at the wholesaler level this loss is compensated more than the loss at pharmacy level

⁵ Same absolute margin as originator + increased legal discount (17% vs. 2.5%)

⁶ Only in case of emergency

| SECTION I |

Generic Medicines Distribution (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
How are generic medicines distributed in your country?																								
Industry/ wholesaler/ pharmacy	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	19	0	1	20
Industry/ pharmacy	-	Yes	Yes	Yes	-	No	No	Yes	Yes	-	Yes	Yes	-	-	No	Yes	-	-	No	Yes	9	4	7	20
What is the role of wholesalers?																								
Logistic partner	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	-	Yes	-	Yes	Yes	Yes	16	0	4	20
Business partner	-	Yes	-	Yes	-	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	-	No	Yes	10	5	5	20
Other	No	No	No	No	No	No	Yes	Yes	Yes	No	No	No	No	Yes	-	No	Yes	Yes	No	Yes ¹	7	12	1	20

¹ Also as virtual manufacturer



Generic Medicines Distribution (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
Pharmacy profit is based on:																									
Delivery, fixed fee	No	Yes	No	Yes	-	No	No	Yes	No	No	No	No	No	No	No	No	-	No	No	No	4	14	2	20	
Fixed margin	Yes	No	Yes	Yes	-	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	-	Yes	No	Yes	12	6	2	20	
Other	No	Yes ¹	No	No	-	Yes ²	Yes	Yes ³	Yes ⁴	No	Yes ⁵	No	Yes ⁶	No	No	Yes ⁷	-	No	Yes ⁸	No	9	9	2	20	
If not, what is the % fixed for wholesalers and pharmacies?																									
Wholesalers (%)	7-17.5	15	6-9	8.5	10-30 ⁹	-	-	9.93	-	12	6.65	-	-	- ¹⁰	8.9	8	-	4-5	2-9	-	-	-	-	20	
Pharmacists (%)	3.9-55	-	18-22	-	10-30 ⁹	-	-	26.1	-	26	26,7	-	-	7 ¹¹	8.9	20	-	17-33	12-25	-	-	-	-	20	

¹ Fixed amount per delivered pack (3.88 €) + « economic » margin in % (6.04), calculated on the ex-factory price

² Discounts to pharmacies are possible

³ Legal discount on invoice : 17% for generic medicines and TFR vs. 2.5% for originators

⁴ Combination of fixed price 8.10€+ 3% of public price (list price)

⁵ The remaining 8% is distributed, according to market forces, to the supply chain as an incentive to prescribe generic medicines. Usually, this % is summed up with wholesaler margin or directly with pharmacist margin in case of direct sale from company to pharmacy

⁶ Dispensing fee and still some discount

⁷ Commercial discounts

⁸ A regressive margin structure is in place where cheaper products have higher margins

⁹ A shared margin between both 10-30%. the higher the price, the lower the margin percentage

¹⁰ Not regulated. Wholesaler's margin is difference between price from generic medicine company and price to pharmacy (reimbursed price)

¹¹ 7% on the first 25€/price to pharmacy to wholesaler, 4% on the amount above 25€ when prices are higher

Generic Medicines Distribution (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Pharmacy profit is based on:																								
The public sales price	-	-	Yes	No	Yes	-	-	No	Yes	-	Yes	No	-	-	Yes	Yes	Yes	Yes	-	-	8	3	9	20
Other	-	-	No	Yes ¹	-	-	-	Yes ²	Yes ³	Yes	-	-	-	Yes ⁴	-	No	-	-	Yes	-	6	2	12	20
Are discounts/ rebates legally allowed?	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes ⁵	Yes	Yes	17	3	0	20
If yes, what is the max % that can be offered?	No limit	No limit	-	8.5	No limit	-	-	17	-	No limit	8	No limit	-	-	No limit	No limit	10	-	No limit	-	4	8	8	20

¹ Based on the wholesale price

² Based on manufacturer price

³ Wholesalers' mark-ups are capped for prescription medicines as well as reimbursable OTC drugs. Maximum mark-ups are defined by law according to a sliding-scale that includes both mark-ups expressed as a percentage of ex-factory prices and fixed amounts

⁴ For pharmacies, a fixed margin on price they pay to wholesaler

⁵ On patent product but not on generic medicines



| SECTION J | Marketing Authorisation (1/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Is a Marketing Authorisation (MA) necessary to apply for generic medicines price?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	No	No	16	3	1	20
Is a Marketing Authorisation necessary to apply for generic medicines reimbursement?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	19	1	0	20
Does the legal basis for MA have an impact on pricing and/or reimbursement of generic medicines?	-	No	No	No	No	No	No	-	No	-	No	No	-	No	No	Yes	No	No	No	No	1	15	4	20
Do the small differences in therapeutic indications between the generic and originator product have an impact on pricing and/or reimbursement of generic medicines?	-	Yes	No	No	No	No	No	No	No	-	Yes	Yes	No	No	No	No	No	No	No	No	3	15	2	20

Marketing Authorisation (2/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
The application for price and reimbursement of a generic medicine:																								
Is the same process	Yes	No	No	No	Yes	Yes	Yes	Yes	-	Yes	Yes	No	No	No	Yes	No	No	Yes	No	No	9	10	1	20
Are separate processes	No	Yes	Yes	Yes	No	No	No	No	-	No	No	Yes	No	Yes	No	Yes	Yes	No	Yes	No	8	11	1	20
On average, how long does it take for a generic medicine to receive its price approval from the day of application?	150d	30d	90d	180d	150-240d ¹	14d ²	30d	60d	-	30d	90d	30d	30d	-	180d	21d	30d	5-30d ³	100d	-	-	-	3	20
Are legal timelines for prices respected?	Yes	Yes	Yes	Yes	No	-	Yes	-	No	-	No	Yes	-	Yes	No	Yes	No	Yes	No	-	9	6	5	20
How long does it take for a generic medicine to receive its reimbursement approval from the day of application?	150d	180d	30d	180d	150-500d ¹	14d	30d	60d	-	30d	90d	180d	30d	-	180d	120d	30d	5-30d ⁴	150d	-	-	-	3	20
Are legal timelines for reimbursement respected?	Yes	Yes	Yes	Yes	No	-	Yes	-	No	-	-	Yes	Yes	Yes	No	No	No	Yes	No	-	9	6	5	20

¹ Median: 300d

² You enter the product in the price list and it is effective 14 days later

³ It takes 5 days to get the price application approved but the approved price is effective the following month

⁴ Same process as the price approval



Marketing Authorisation (3/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total	
Which of the following options for the generic medicine name are legally allowed:																									
INN + Company name + Strength + Form	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	Yes	Yes	Yes	Yes	Yes	No	Yes	18	1	1	20	
INN + Fantasy name + Strength + Form	No	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	-	No	Yes	Yes	Yes	No	No	Yes	10	9	1	20	
Fantasy name + Company name + Strength + Form application?	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	-	No	No	Yes	Yes	No	No	No	10	9	1	20	
Fantasy name + Strength + Form	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	-	No	No	Yes	No	Yes	No	No	12	7	1	20	
Other	No	No	No	No	No	No	No	Yes ¹	Yes ²	No	No	No	-	No	No	No	-	-	Yes ³	-	3	13	4	20	

¹ Fantasy name+ GE+ Strength

² The naming options are in practice not legally determined, but those above are most commonly found

³ INN+ Fantasy name+ Company name Strength+ Form

Marketing Authorisation (4/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Is the granting of a generic medicine MA price allowed during the patent/SPC period?	No	Yes	No	No	No	-	Yes	Yes	No	No	Yes	No	-	Yes	Yes	Yes	No	Yes	Yes	-	9	8	3	20
If yes, it is based on:																								
Clear provision in the legislation	-	-	-	-	-	-	No	No	-	-	No	-	-	No	-	No	-	-	Yes	-	1	5	14	20
Outcomes of court cases	-	-	-	-	-	-	No	No	-	-	Yes	-	-	No	-	No	-	-	No	-	1	5	14	20
Current practices without any particular legal provision	-	-	-	-	-	-	Yes	No	-	-	No	-	-	No	-	No	-	-	No	-	1	5	14	20
Other	-	-	-	-	-	-	No	Yes ¹	-	-	No	-	-	Yes ²	-	Yes ³	-	-	No	-	3	3	14	20

¹ Convention CEPS- Industry

² No product patent in Norway until 1992. The first product patented drugs will be in 2012-2013. One can launch product patented generic medicines since in Norway there are only process patents so far

³ There is no legal restriction. However, there are some legal procedures (preliminary injunctions) from originator companies blocking regulatory steps for generic medicines, namely at MA and price level-patent linkage



Marketing Authorisation (5/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Is the granting of generic medicines products reimbursement allowed during the patent/SPC period?	Yes	Yes	No	No	No	-	Yes	Yes	No	No	Yes	No	No	Yes	Yes	Yes	No	Yes	No	-	9	9	2	20
If yes, it is based on:																								
Clear provision in the legislation	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	No	-	-	-	-	0	2	18	20
Outcomes of court cases	-	-	-	-	-	-	-	No	-	-	-	-	-	-	-	No	-	-	-	-	0	2	18	20
Current practices without any particular legal provision	-	-	-	-	-	-	-	No	-	-	Yes	-	-	-	-	No	-	-	-	-	1	2	17	20
Other	-	-	-	-	-	-	-	Yes ¹	-	-	-	-	-	Yes ²	-	Yes ³	-	-	-	-	3	0	17	20

¹Convention CEPS- Industry

²No product patent in Norway until 1992. The first product patented drugs will be in 2012-2013. One can launch product patented generic medicine since in Norway there are only process patents so far

³There is no legal restriction. However, there are some legal procedures (preliminary injunctions) from originator companies blocking regulatory steps for generic medicine, namely at MA and price level-patent linkage

| SECTION K |
General Information about Generic Medicines (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Yes	Total No	Total NA	Total
Has Government taken measures to stimulate the prescribing and dispensing of generic medicines in 2010?	No	No	No	Yes	No	No	No	No	No	Yes	Yes	-	Yes	No	No	Yes	Yes	No	No	No	6	13	1	20



General Information about Generic Medicines (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Number	Total N/A	Total
What is the number people employed by generic medicines companies in 2010?	550	600	10000	650	5500	-	-	2000	-	-	5000	-	800 ¹	300 ²	25000	1890	-	200	15000	3000	70490	6	20
What is the number of people indirectly employed by generic medicines companies in 2010?	-	1500	-	-	-	-	-	10000	-	-	6000	-	-	-	20000	-	-	-	-	-	37500	16	20

¹ Full time employment

² In typical generic medicine only companies, they generally employ between 1 and 5 persons. In Norway, there are about 100 generic companies with mixed product types

General Information about Generic Medicines (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Rep.	Denmark	Finland	France	Germany	Hungary	Italy	Latvia	Netherlands	Norway	Poland	Portugal	Spain	Sweden	Turkey	United Kingdom	Total Number	Total N/A	Total
What annual savings are realised through the use of generic medicines in 2010?	0.10 BN	-	-	-	-	1.10 BN	-	1.70 BN	10.10 BN	-	0.3 BN	-	1.30 BN	-	0.70 BN	-	-	0.56 BN	0.37 BN	9.82 BN	26 BN	10	20
What is the total investment in R&D of generic medicines in 2010?	-	-	-	-	2M	-	-	-	-	-	15.30 M	-	-	-	-	-	-	-	-	-	17.30 M	18	20

Corrigendum

Please see below the updates that have been made to the initial version of this document:

- Austria
 - o P.7, maximum price: yes
- Spain
 - o P.30, Pharmacy profit is based on: the public sales price: yes | P.30, Are discounts/rebates legally allowed: yes | P.30, If yes, what is the max % that can be offered: 10%
 P.31, Is a Marketing Authorisation (MA) necessary to apply for generic medicines price: yes | P.31, Is a Marketing Authorisation necessary to apply for generic medicines reimbursement: yes
 P.31, Does the legal basis for MA have an impact on pricing and/ or reimbursement of generic medicines: no | P.31, Do the small differences in therapeutic indications between the generic and originator product have an impact on pricing and/ or reimbursement of generic medicines: no | P.32, The application for price and reimbursement of a generic medicine: is the same process: no | P.32, Are separated processes: yes | P.32, On average, how long does it take for a generic medicine to receive its price approval from the day of application: 30d | P.32, Are legal timelines for prices respected: no | P.32, How long does it take for a generic medicine to receive its reimbursement approval from the day of application: 30d | P.32, Are legal timelines for reimbursement respected: no | P.33, Which of the following options for the generic medicine name are legally allowed: INN+ Company name= Strength= Form: yes | P.33, INN+ Fantasy name+ Strength+ Form: yes | P.33, Fantasy name+ Company name+ Strength+ Form application: yes | P.33, Fantasy name+ Strength+ Form: no | P.34, Is the granting of a generic medicine MA price allowed during the patent/ SPC period: no | P.35, Is the granting of a generic medicine reimbursement allowed during the patent/ SPC period | P.36, Has Government taken measures to stimulate the prescribing and dispensing of generic medicines in 2010, yes
- Sweden
 - o P.18, what is the general public/ patient's perception of and attitude towards the use of generic medicines?
 - Positive: yes
 - Negative: no
- Turkey
 - o If you have a price regulated system, are prices set based on :
 - P.7, % below the originator: no | P.7, Negotiable: no | P.7, Other: Yes | P. 22, can doctors prevent generic medicines substitution : no | P.22, if yes: by a ticking box: no | P. 24, the cheapest generic medicine available, without reference to the doctor: no | P.35, Outcomes of court cases: (-)



The EGA is the official representative body of the European generic and biosimilar medicines industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.



Making Medicines Affordable

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